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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,760	07/31/2001	Paul Douglas Scotti	514274-2001	6462
7590	06/23/2004			
Frommer Lawrence & Haug 745 Fifth Avenue New York, NY 10151			EXAMINER PAK, YONG D	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,760

Applicant(s)

SCOTTI ET AL.

Examiner

Yong D Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 10, 12, 13 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 is/are allowed.
- 6) ☒ Claim(s) 9, 12, 13 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Art Unit: 1652

DETAILED ACTION

This application is a 371 of PCT/NZ99/00227.

The amendment filed on April 5, 2004, amending claims 9-10, 12 and 25, has been entered.

Claims 9, 10, 12, 13 and 25 are pending.

Response to Arguments

Claim Rejections - 35 USC § 112

Applicant's arguments filed on February 27, 2004, with respect to the rejection of claims 10, 12 and 13 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 10, 12 and 13 are withdrawn.

Applicant's arguments filed on February 27, 2004, with respect to the rejection of claims 9, 12-13 and 25 under 35 U.S.C. 112, 1st paragraph have been fully considered and are not persuasive.

Claims 9, 12-13 and 25 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1652

Applicants argue that the claims are not drawn to serine protease inhibitor fragments. Previous claim 9 was drawn to a polypeptide having a genus of fragments of SEQ ID NO:7. Presently, the claims are drawn to a polypeptide derived from any source and comprising a fragment of SEQ ID NO:7. However, claims are drawn to a large variable genus with the potentiality of encompassing many different polypeptides having serine protease inhibitor activity. The peptide of SEQ ID NO:1 is not representative of a full length polypeptide having serine protease activity (specification, page 16). A description of only 10 amino acids, which amounts to less than 5% of the only serine protease inhibitor described by the specification, is not enough to describe such a large genus.

Applicants argue that the specification describes SEQ ID NO:1 as imparting serine protease inhibitor activity for a polypeptide of 55kDa. The examiner disagrees.

The specification teaches that there is homology between the 10 amino acids (SEQ ID NO:1) from the N-terminus of SEQ ID NO:7 to a anti-thrombin protein sequence. However, the specification does not describe that SEQ ID NO:1 imparts serine protease inhibitor activity to a polypeptide. Further, the claims also are not drawn to a pernin polypeptide comprising SEQ ID NO:1 but to a generic polypeptide derived from any source having serine protease inhibitor activity.

Applicants argue that the newly amended claim 25 describes sufficient structural limitation. The examiner disagrees. The claim is drawn to a wide genus encompassing many different serine protease inhibitors. The source of the inhibitor and the apparent molecular weight/density gradient data is not enough to describe the polypeptides

Art Unit: 1652

encompassed in the claim. Physical properties such as molecular weight and density gradient data are not sufficient in describing a polypeptide because such physical properties do not provide any structural information on the polypeptide nor provide any characteristics or properties to identify the polypeptide.

Claim 9, 12-13 and 25 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a serine protease of SEQ ID:7, does not reasonably provide enablement for fragments of SEQ ID NO:7 with unlimited structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the claims are not drawn to polypeptides having unlimited structure but that the claims are drawn to a polypeptide having specific limitations to its structure. The examiner disagrees.

As discussed above, the specification does not teach that SEQ ID NO:1 imparts serine protease inhibitor activity to a polypeptide. The claims limit the structure of the polypeptide to SEQ ID NO:1, which amounts to less than 5% of the only serine protease inhibitor described by the specification. The claims limit the polypeptides to a specific molecular weight. Such physical characteristics do not aid in elucidating structural information on the polypeptide nor provide any characteristics or properties to identify the polypeptide. A skilled artisan would not recognize a polypeptide based on molecular weight, function and a description of only 10 amino acids and would require

Art Unit: 1652

undue experimentation to identify/make a serine protease inhibitor from Perna canaliculus equipped with only knowing 10 amino acids of its structure and its molecular weight.

Allowable Subject Matter

Claim 10 is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1652


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak

June 16, 2004


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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